



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,178	07/06/2001	Masayasu Sentoh	0397-0430P	9769

2292 7590 07/08/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 07/08/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,178

Applicant(s)

SENTOH, MASAYASU

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 3, 5 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear which sliders (3-5) does applicant intend to be first, second and third members. It is hereby broadly interpreted that slide member 4 is the second member and slide member 3 and 5 can be either first or third members, and springs 21 or 22 maybe consider the elastic member.

For the purpose of examination slide 5 is the third member, slide 3 is the first member, and spring 22 is the elastic member.

Claims 9-11 fail to further structurally limit the apparatus of claim. Claim 9 is directed to the contents of the vessel. However the vessel is not positively recited as an element of the invention, therefore, the contents of the vessel have no patentable weight within the scope of the claims. Claims 10 and 11 are directed to the general intended use of the suction device and do not further limit the structure of the claimed suction apparatus.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-2, 4, 6-7, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilks US 5,578,495 in view of Stettler US 5,240,679 or Preston et al. US 6,274,087.

Wilks disclosure is related to automated fluid injection devices, particularly automated needle syringes, have gained wide acceptance by industry and by the scientific and medical communities. This is because these devices are generally capable of dispensing very small, accurately measured quantities of fluid specimens on the order of a few microliters, generally a fractional part of a microliter. In the operation of these devices many samples are prepared in advance, the specimens placed in vials, the vials placed in a magazine, or tray and the samples run with minimal operating labor. Typically, e.g., septum covered bottles, or vials charged with a fluid specimen, are

transported in seriatim via a magazine to a station adjacent a probe assembly, a needle of the probe assembly is projected through the septum of a vial and employed as a conduit to convey a portion of the fluid specimen to the barrel of the syringe. The circuit through which the specimen is conducted, and barrel and needle of the syringe are cleaned, purged and a quantity of the fluid specimen is measured out and injected via the needle end of the syringe into the inlet of an analytical instrument, e.g., a G.C. or mass spectrometer.

The solids preparation and extraction sub-assembly 200, as shown by any of FIGS. 1-4, includes generally an electrical heater, or oven 210, and an elevator assembly 220 inclusive of an upper carriage section 222₂ and a lower carriage section 222.sub.1. It further includes an elevator motor 221 for raising and lowering the elevator assembly 220, and a stir motor 223 for inductive rotation of the magnetic stir bar 258 contained within vial 250. The electric oven 210, which is secured in place in fixed position upon a generally upright frame structure, housing and tower assembly, below the plate 211, is constituted of an electric heating element-containing wall, to which current is supplied via electrical leads (not shown) surrounding an open space within which the elevator carriage 222, supported upon a generally upright frame structure, housing and tower assembly, and carrying a vial, or bottle 250 within which a solution can be added to contact a solid or semi-solids material, can be raised, housed and heated. The electrical heating element 213, it will be observed, is located between side walls 214₁, 214.sub.2 of the heater, and on one side thereof is provided insulation 215. Within the plate 211 is provided an opening or aperture through which the pair of

concentrically mounted tubular needles 212 is projected, and rigidly retained in fixed vertical position. The inner needle 212₁ is connected via a valved line 212.sub.1A and line 212_{1C} (with valved line 212_{1B} closed) to a supply source through which a liquid solvent, suitably a preheated liquid solvent if desired, can be introduced (FIG. 3). Alternatively, a gas can be supplied to the inner needle 212₁ via lines 212_{1B}, with 212_{1C} (with line 212_{1A} closed; see FIG. 4). The outer needle 212₂, with the inner needle 212.sub.1, provides an annulus through which gas from the headspace above the level of the liquid in bottle 250 can be passed via outlet line 212_{2A} (FIG. 4). The elevator assembly 220, constituted of a carriage 222 provided with lower and upper elevator sections 222₁ (first member) 222₂ (second member) are slidably mounted in a vertical groove (not shown) of the housing or tower assembly for upward and downward movement within the support structure, or tower. The elevator carriage 222 can be reciprocated by the elevator motor 221, the shaft (not shown) of which is geared thereto by a mechanism (not shown).

Wilks does not disclose a third moveable member and an elastic compressible spacer between the second and third members.

Preston et al. disclose an invention that relates to a diagnostic medical device, and in particular to a blood cell analyzer (hematology) which by manual or automatic operation withdraws and analyzes a minimal amount of blood that is stored in open or sealed vials. The analyzer includes a manually operated self cleaning sampling device for open vials and an automated self cleaning sampling device for sealed vials fitted with a pierceable cap.

FIG. 2 shows a preferred embodiment of the variable size vial holder and cap piercer 11. This apparatus comprises a frame 12, an adjustable holder 14, a top plate 16, a cup 18, an extendable and retractable needle 20, and a driver 22 for extending and retracting the needle 20. A multi-lobe cam 22a with associated position switches 24 is used to detect needle position. In addition, a safety switch 24a is used for interlocking the driver with the holder 14 so that the driver 22 cannot extend the needle 20 when a vial 23 is not fully engaged in and held by the holder 14 (third member).

In the preferred embodiment, the holder 14 is an over center spring (elastic member) loaded mechanism of the configuration shown in FIG. 4. The holder 14 includes a U-shaped clamp 32 adjustably mounted to the frame 12 and an oblong-shaped tongue 34 mounted between two arms 33 of the clamp 32. The tongue 34 is retained in the clamp 32 by a pin 36 which extends across the width of the clamp 32. The tongue 34 has a beveled surface 35 and pivots about the axis of the pin 36.

Stettler discloses an apparatus for the automatic introduction of a pipetting insert through the stopper of a sample vessel sealed by the stopper and containing a sample.

The apparatus shown in FIG. 1 comprises, inter alia, an entry device 51 on a platform 46, positioned on the base of the apparatus under the press-in means 55 (third member) to receive and position the sample vessel 13, a feed means 52 which takes individual pipetting inserts 11 successively to a delivery station 53, and a press-in means 55 movable by a drive means 54 and containing a plunger 41 by means of which

a pipetting insert 11 is taken from the delivery station 53 and introduced into the stopper 14 of a sample vessel 13 contained in the entry device 51.

The press-in means 55 and hence the plunger 41 are moved downwards by drive-means 54 to an extent such that the pipetting insert 11 is pressed as deeply as possible into the stopper 14 and assumes the position shown in FIG. 3. The maximum tension of the spring (elastic member) 43 is achieved in this position and the top end of the plunger 41 is situated directly adjacent the electromagnet 42. At this time voltage sufficient to hold the plunger 41 in the press-in means 55 in the position shown in FIG. 3 against the force exerted by the tensioned spring 43 is applied to the electro-magnet 42 by means of suitable leads (not shown). Immediately thereafter the press-in means 55 is raised by means of drive-means 54 so that the plunger 41 is withdrawn from the pipetting insert 11, which is left in the stopper 14. As shown in FIG. 4, the plunger 41 remains held by the electromagnet 42.

To detect the position of a pipetting insert 11 inserted in a stopper 14, the press-in means 55 is moved down from the position shown in FIG. 1 by means of drive-in means 54 and introduced into the cavity of the pipetting insert 11. During this movement the sensor 57 detects the time at which an upward movement of the top part of the plunger 41 starts. If this upward movement starts before the press-in means 55 has covered a predetermined distance, the level-sensing means detects and signals that the pipetting insert 11 has not been inserted sufficiently deeply in the stopper 14. Repetition of the pressing-in operation and impact is then initiated by an appropriate output signal from the level sensing means.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Wilks to include an automated reciprocating moveable needle means and spring in order to allow for adequate pressure to insert and remove the needle from vessels comprising seals manufactured from various materials.

Allowable Subject Matter

7. Claims 3, 5, and 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest a device that comprises a drive source that comprises an air cylinder having a piston rod, the air cylinder being provided on the third member and a distal end of the piston rod being connected to the first member and a second member the includes a washing bath for washing the suction needle.

Conclusion


9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gerstel et al., Brockwell, Lin et al., Levy, Preston et al. (,903), Classon et al., Anami, Golias et al., and Wilson et al. disclose devices that employ needles to access containers.

Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

brg
July 3, 2003